

REMARKS

Claims 15-36 were pending in this Application as of the Office Action of January 15, 2010 (with claim 37 having been withdrawn). Claims 15-20, 22-23, and 36 are amended with this Response. Claims 16, 21, 26-27, and 37 are cancelled. Claims 38 and 39 are added. The Examiner rejections will now be respectfully addressed in turn.

Rejections under 35 U.S.C 112, second paragraph

Claims 15, 20, 21, and 36 have been rejected under 35 U.S.C. 112, second paragraph as allegedly being indefinite. In Response, Applicant respectfully amends claims 15, 20, and 36, and cancels claim 21.

Rejections under 35 U.S.C. 102(e)

Claims 15-16, 18-20, 26, 29-30, and 35 stand rejected under 35 U.S.C. 102(e) as being anticipated by United States Publication No. 2004/0193273 to Huang (“Huang” hereinafter). Applicant respectfully traverses this rejection

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicant’s claim 15 recites, *inter alia*:

“an outer ring portion disposed outwardly of the core portion and of the hollow shaft, wherein the outer ring portion comprises a first surface and a second surface opposed to the first surface, the first and second surfaces of the outer ring portion being respectively affixed to inner surfaces of the two half-shells.”

Huang does not teach a compression pad including an outer ring portion that is disposed outwardly of a core portion and hollow shaft containing the core portion, wherein first and second opposing surfaces of the outer ring portion are respectively affixed to inner surfaces of two half-shells. In fact, Huang fails to teach an outer ring portion as claimed that is (or even could be)

affixed to anything. Instead, and with pertinent reference to paragraph 0031 and Figures 1-2, Huang teaches an annular chamber A formed in the prosthetic intervertebral disc and filled with a buffer “liquid.” This liquid, like any other liquid, is obviously incapable of being affixed to anything, and is therefore not taught to for any affixing in Huang.

In addition, it should be noted that the only affixable/affixed pad material taught in Huang is that of lower portion 31, which is taught to be secured to lower plate 2 at an area *entirely within the shaft 24* (please see paragraph 0034 and Figures 1-2). This affixing to a pad material entirely within the shaft 24 is contrary to Applicant’s claimed affixing at a material disposed outwardly of the shaft.

For at least the above reasons, Applicant respectfully asserts that Huang fails to teach an outer ring portion disposed outwardly of a shaft and affixed at opposing ends to the inner shell surfaces, as required by Applicant’s claims 15-16, 18-20, 26, 29-30, and 35. Accordingly, Huang fails to anticipate Applicant’s claims 15-16, 18-20, 26, 29-30, and 35

Regarding the Examiner’s comments directed to the term “secured” (page 9 of the Office Action), Applicant respectfully points out that the claims now recite the term “affixed,” which is defined by dictionary.com as, “to fasten, join, or attach.” This affixing is further specified in new claim 38 to be accomplished via a mechanical fastener, such as the lug 18 disclosed in Applicant’s Specification and Figures.

Furthermore, and with regards to any potential 103 rejections of these claims, Applicant respectfully notes that if the Huang prosthesis were to be *pro arguendo* modified such that the liquid buffer were replaced by a harder, non-liquid material to which the shells may be affixed, it would not be possible for the fluid pumping action discussed at paragraph 0051 to occur (a solid, affixable material could not flow in such a manner). Accordingly, such a modification would be improper under MPEP 2143.01V.

Still further with regards to any potential 103 rejections of these claims, if the Huang

prosthesis were to be *pro arguendo* modified such that any portion of the cushion coupler 3 were affixed at opposing surfaces to the upper and shells/lower fusion members 1 and 2, the rotational contact taught in Huang would no longer be possibly. Without this rotational contact, the contacting surfaces (and overall prosthesis) of Huang would be rendered inoperable for its intended purposes. Accordingly, such a modification would also be improper under MPEP 2143.01V.

Applicant additionally and respectfully notes that the above discussed affixing of the first and second surfaces of the outer ring portion to inner surfaces of the two half-shells provides a restoring torque in torsion during the displacement of the spinal column of a patient fitted with a prosthesis. This advantageously allows the anatomic biomechanics of the replaced intervertebral disc to itself be restored, preserving the patient's ligaments.

Rejections under 35 U.S.C. 103(a)

Claims 22-23, 25, 28, and 32-33 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Huang. Applicant respectfully traverses this rejection.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art and that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

Claims 22-23, 25, 28, and 32-33 depend from claim 15. As such, for at least the reasons set forth in the above 102 Remarks, Applicant respectfully asserts that Huang does not teach every element of Applicant's claims 22-23, 25, 28, and 32-33. Accordingly, Applicant respectfully submits that *prima facie* obviousness does not exist regarding claims 22-23, 25, 28, and 32-33 with respect to Huang or any proposed modification thereto.

Claims 17, 21, 24, 27, and 36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Huang in view of United States Patent No. 5,674,294 to Bainville (“Bainville” hereinafter). Applicant respectfully traverses this rejection, noting that claims 21 and 27 have been rejected.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art and that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

Applicant first notes that claims 17 and 24 (by virtue of their dependency from claim 15) and claim 36 recite *inter alia*,

“an outer ring portion disposed outwardly of the core portion and of the hollow shaft, wherein the outer ring portion comprises a first surface and a second surface opposed to the first surface, the first and second surfaces of the outer ring portion being respectively affixed to inner surfaces of the two half-shells.”

As such, the lower portion 31 of Huang cannot be equated with Applicant’s outer ring portion (as alleged by the Examiner) is now recited in the amended claims. This is because the lower portion 31 *is disposed within* the shaft 24 (please see Figures 1 and 2 of Huang). As Bainville fails to remedy this deficiency, or any of the Huang deficiencies discussed in the 102 remarks, Applicant respectfully asserts that the proposed combination of Huang and Bainville fails to teach every element of Applicant’s claims 17, 24, and 36. Accordingly, Applicant respectfully submits that *prima facie* obviousness does not exist regarding remaining claims 17, 24, and 36 with respect to the proposed combination of Huang and Bainville.

With more specific reference to claim 36, there is further recited *inter alia*,

“wherein the core portion of the compression pad comprises a first material and the outer

ring portion of the compression pad comprises a second material, the second material being harder than the first material and being a polycarbonate urethane type material.”

Huang does not teach an outer ring material as claimed that is harder than an inner core material as claimed. On the contrary, Huang quite oppositely teaches an outer liquid buffer (in the annular chamber A) that is inherently less rigid than the inner elastomer cushion coupler 3. In addition, this outer liquid buffer is obviously not a polycarbonate urethane type material, as is now claimed. As neither Huang nor Bainville teach core and outer portion such as they are now recited in the amended claims, Bainville cannot be used remedy this deficiency

Furthermore, Applicant respectfully notes that if the Huang prosthesis were to be modified (or combined with Bainville) such that the liquid buffer were replaced by a harder than that which comprises the elastomer cushion coupler 3, it would not be possible for the fluid pumping action discussed at paragraph 0051 to occur (a solid, affixable material could not flow in such a manner). Accordingly, such a modification would be improper under MPEP 2143.01V.

Here again, Applicant respectfully submits that *prima facie* obviousness does not exist regarding claim 36 with respect to the proposed combination of Huang and Bainville.

Applicant additionally and respectfully notes that making the outer ring portion of a polycarbonate urethane type material induces an asymmetric deformation of the disc prosthesis according to the invention during extension/flexion of said disc prosthesis. Said asymmetric deformation advantageously results from that fact that the compression strength of a polycarbonate urethane type material corresponds substantially to the double of the tensile strength thereof. In addition, this asymmetric deformation allows for an instant center of rotation located outside of the space defined between the two half-shells, which acts to restore anatomic biomechanics of the replaced intervertebral disc.

Claims 31 and 34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Huang in view of Bainville and United States Publication no. 2003/0074067 to Errico (“Errico” hereinafter). Applicant respectfully traverses this rejection.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art and that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

Claims 31 and 34 depend from claim 15. As such, for at least the reasons set forth in the above 102 Remarks, Applicant respectfully asserts that Huang does not teach every element of Applicant's claims 22-23, 25, 28, and 32-33. As neither Bainville nor Errico remedy the deficiencies of Huang, Applicant further and respectfully asserts that any proposed combination of Huang, Bainville, and Errico also fails to teach every element of Applicant's claims. Accordingly, Applicant respectfully submits that *prima facie* obviousness does not exist regarding claims 31 and 34 with respect to the proposed combination of Huang, Bainville, and Errico.

New Claims 38 and 39

New claim 38 recites *inter alia*,

“wherein the first and second surfaces of the outer ring portion are respectively affixed to inner surfaces of the two half-shells via a mechanical fastener.”

Applicant respectfully points out, as discussed above, that none of Huang, Bainville, or Errico, teach any such affixing, let alone any such affixing via mechanical fastener.

New claim 39 recites *inter alia*,

“wherein the central zones of the two half shells are each defined by perimetric extents that are closer to a relative midpoint of each respective half shell than any edge of each respective half shell.”

Applicant respectfully points out that none of Huang, Bainville, or Errico, teach a shaft or stud in any such central zone. On the contrary, Huang teaches the skirt 24 to be disposed closer to the edge of the lower shell 2 than the midpoint thereof. This feature is of particular importance in that provision of the hollow shaft in a central zone of the first half-shell allows, in the extreme case of tearing of an interface between the outer ring portion and one of the half-shells, to limit the displacements of said one of the half-shells and therefore to avoid any risk to the patient.

Conclusion

Applicant believes that all of the outstanding objections and rejections have been addressed herein and are now overcome. Entry and consideration hereof and issuance of a Notice of Allowance are respectfully requested.

Applicant hereby petitions for any extension of time under 37 C.F.R. 1.136(a) or 1.136(b) that may be necessary for entry and consideration of the present Reply.

If there are any charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Applicants' attorneys.

The Office is invited to contact applicant's attorneys at the below-listed telephone number concerning this Amendment or otherwise regarding the present application.

Respectfully submitted,
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